

FEB - 1 2001

K003482

14. 510(k) Summary

PROCLUDE-SENSITIVE

Contact: Target Health Inc.
305 Madison Avenue, Suite 2501
New York, NY 10165

Tel: 212 681-2100
Fax: 212 681-2105

Sponsor: ORTEK THERAPEUTICS, INC.
1205 Franklin Avenue
Garden City NY 11530

Tel: 516-248-8453
Fax: 516-739-0822

Device Name: PROCLUDE-SENSITIVE

Trade Name: PROCLUDE-SENSITIVE

Common Name: Cavity varnish

Classification Name: – Sec. 872.3260 Cavity varnish.

Predicate Device/ Company Names and Addresses

Seal and Protect Dental Varnish

Dentsply Preventive Care
York, PA 17404

The predicate device is listed below with its 510(k) clearance number.

PRODUCT NAME	510 (k)	CLEARANCE DATE
Seal and Protect Dental Varnish	K992822	11/17/1999

Description of Device

Cavity varnish is a device that consists of a compound intended to seal open dentinal tubules resulting from the preparation of the tooth for inserting of a filling material such as a dental amalgam and to coat a prepared cavity of a tooth before insertion of restorative materials. A cavity varnish is also intended to prevent penetration of pain-causing stimuli such as tactile, hot/cold, evaporative and osmotic (*i.e.* prevent teeth from being sensitive).

Intended Use

PROCLUDE-SENSITIVE is a topical desensitizing dental cream for the management of sensitive teeth. PROCLUDE-SENSITIVE acts as a protective sealant for exposed dentine. The Indications for Use are:

1. Treatment of hypersensitivity associated with exposed root surface dentin.
2. Reduction of abrasion and erosion of exposed cervical dentin.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

FEB -1 2001

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ortek Therapeutics, Incorporated
C/O Mr. Jules T. Mitchel
Target Health, Incorporated
305 Madison Avenue, Suite 2501
New York 10165

Re: K003482
Trade Name: Proclude-Sensitive
Regulatory Class: II
Product Code: LBH
Dated: November 6, 2000
Received: November 9, 2000

Dear Mr. Mitchel:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

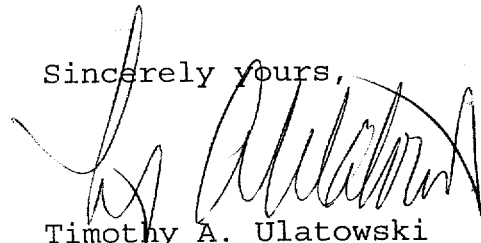
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director

Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

15. Indications For Use

510(k) Number: K003482

Device Name: PROCLUDE-SENSITIVE

Indications For Use:

PROCLUDE-SENSITIVE is a topical desensitizing dental cream for the management of sensitive teeth. PROCLUDE-SENSITIVE is indicated for:

1. Treatment of hypersensitivity associated with exposed root surface dentin.
2. Reduction of abrasion and erosion of exposed cervical dentin.

~~DO NOT WRITE BELOW THIS LINE~~

~~CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)~~

Prescription Use ☒ or Over-The Counter Use ☒

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Gerald W. Shupm
(Division Sign-Off) Ger MSR
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K003482